

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 2003N-0361]

### Anti-Counterfeit Drug Initiative; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting.

---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting on the agency's effort to combat counterfeit drugs. The purpose of the meeting is to enable interested individuals, organizations, and other stakeholders to present information on all aspects of the agency's initiative against counterfeit drugs. FDA is particularly interested in hearing about information related to technology, public education, regulatory and legislative issues, and industry and health professional issues. The agency is also inviting vendors of anti-counterfeit technologies relevant to the pharmaceutical industry to display their products for the educational benefit of FDA and attendees. The objective of the meeting is for FDA to gather information to assist FDA's counterfeit drug task force in finalizing its report, which will include recommendations on steps that FDA, other government agencies, and the private sector can take to minimize the risks to the public from counterfeit drugs entering the supply chain.

**DATES AND TIME:** The public meeting and vendor display will be held on October 15, 2003, from 9 a.m. to 5 p.m. Attendees should send notice of intent to attend the meeting by October 9, 2003. Speakers must register and submit a short summary of the presentation by September 24, 2003. Presenters must send final electronic presentations in Microsoft PowerPoint, Microsoft Word,

or Adobe Portable Document Format (PDF) to FDA by close of business on October 3, 2003.

However, written and electronic comments will be accepted for consideration until November 3, 2003. Vendors must register and submit a brief summary of the product(s) they plan to display by close of business September 24, 2003.

**ADDRESSES:** The public meeting and vendor display will be held at the Four Points Sheraton Bethesda, 8400 Wisconsin Ave., Bethesda, MD 20814, 301–654–1000. The hotel may be reached by Metro using the Medical Center Station on the red line, which is 2 1/2 blocks from the hotel; or you may call the hotel for shuttle bus service. Notice of intent to attend the meeting and requests to present at the meeting should be sent to Elizabeth French, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, FAX 301–594–6777, e-mail: [efrench@oc.fda.gov](mailto:efrench@oc.fda.gov). Requests for vendor display at the meeting should be sent to Karen Strambler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, FAX 301–594–6777, e-mail: [kstrambler@oc.fda.gov](mailto:kstrambler@oc.fda.gov).

*Registration and Requests for Presentation:* If you wish to attend the meeting, please notify Elizabeth French (see **ADDRESSES**). If you wish to present at the public meeting, please submit your request and a summary of your presentation to Elizabeth French at FDA (see **ADDRESSES**). Requests should be identified with the docket number listed in the heading of this document.

Requests to present should contain the following items:

- Presenter's name;
- Address;

- Telephone number;
- E-mail address;
- Affiliation, if any;
- Summary of the presentation; and
- Approximate amount of time requested for the presentation.

FDA encourages persons and groups having similar interests to consolidate their information and present it through a single representative, if possible, to enable a broad range of views to be presented. After reviewing the requests to present, the agency intends to schedule each appearance and notify each participant by e-mail or telephone of the time allotted to the person and the approximate time the person's presentation is scheduled to begin.

Presenters must send final electronic presentations in Microsoft PowerPoint, Microsoft Word, or PDF to FDA by close of business on October 3, 2003.

*Registration and Request for Vendors Displays:*

In addition, there will be an opportunity for vendors of authentication and track and trace anti-counterfeiting technologies to display their products in a room adjacent to the public meeting. The purpose of these displays is to educate FDA and other attendees of the types of anti-counterfeit technologies that are currently available. FDA is particularly interested in vendors displaying products that have the following features:

- Product is currently in commercial use or production;
- Product (or closely similar product) is currently being used in the pharmaceutical distribution system or that has clear applicability to authenticating or tracking pharmaceuticals (e.g., are easily incorporated into the manufacturing process, packaging, and/or labeling of drugs and biologics);

- Track/trace products that have the ability to locate the product throughout the distribution chain from the time of manufacture to the time sale to a consumer;
- Track/trace products that have the ability to be read and used by each entity (or individual) having physical contact with the pharmaceutical;
- Covert authentication technologies that are identifiable by one or more points in the distribution chain (i.e. by wholesalers, repackers, retailers, and health care entities); and
- Covert forensic technologies that are identifiable by a sophisticated analytical laboratory and the manufacturer.

FDA is not interested in having technologies displayed that are not in production or current commercial use, and that are not applicable to pharmaceuticals. For example, technologies that are not easily incorporated into the manufacture, packaging, and/or labeling of pharmaceuticals may not be appropriate for display. Vendors should take these factors into account prior to determining which products to display.

Because of limited space availability, all vendor requests may not be accommodated. If you wish to have a display at the public meeting, please submit your request and the following information to Karen Strambler (see **ADDRESSES**). Requests should be identified with the docket number listed in the heading of this document. Space available for display will be determined based on the number of registrants and total space available; however, the agency anticipates that of those that can be accommodated, vendors will each be provided with, at a minimum, a 4- by 3-foot table for table top display.

Requests to display should contain the following items:

- Presenter's name,
- Address,

- Telephone number,
- Affiliation,
- Product(s) for display, and
- Brief summary of how the anti-counterfeit technology meets the criteria

listed in the previous list items.

After reviewing the requests to display, FDA intends to notify each vendor by e-mail or telephone whether there is space available for display.

*For Information Regarding This Notice:* Poppy Kendall, Office of Policy (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-9278, FAX 301-594-6777, e-mail: [poppy.kendall@fda.gov](mailto:poppy.kendall@fda.gov).

If you need special accommodations due to disability, please inform Elizabeth French (see **ADDRESSES**).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Counterfeit drugs pose potentially serious public health and safety concerns. They may contain only inactive ingredients, incorrect ingredients, improper dosages, dangerous subpotent or superpotent ingredients, or even adventitious agents or contaminants such as harmful bacteria. In the United States, drug counterfeiting is a relatively rare event. Although FDA believes domestic counterfeiting is not widespread, the agency has recently seen an increase in counterfeiting activities as well as a more sophisticated ability to introduce finished dosage counterfeits into the otherwise legitimate drug distribution channels. During the late 1990's, FDA counterfeit drug investigations averaged about five per year. Since 2000, however, FDA counterfeit drug investigations have increased to an average of over 20 per year.

On July 16, 2003, FDA announced an initiative to more aggressively protect American consumers from the risks associated with counterfeit drugs and reduce the possibility of potentially unsafe counterfeit drugs reaching consumers. As part of this effort, FDA established an internal task force that will develop recommendations for steps that FDA, other government agencies, and the private sector can take to minimize the risks to the public from counterfeit drugs getting into the supply chain. Some of the areas that FDA's task force is exploring are included in the following topics:

- *Technology*: Assess the extent to which currently available and potential technologies can help assure the authenticity of drugs;
- *Regulatory/Legislative Issues*: Evaluate potential State and Federal regulatory and legislative changes that could be made to strengthen the nation's protections against counterfeiting;
- *Public Education*: Evaluate ways to educate consumers and health providers on steps they can take to minimize risks associated with counterfeit drugs as well as what to look for and do if they suspect they have received a counterfeit drug;
- *Industry and Health Professional Issues*: Identify actions industry and health professionals can take to prevent, detect, and respond to counterfeit drugs.

The task force anticipates the following deliverables:

- Interim task force report to be released in September 2003. We intend to include preliminary findings on which all interested parties may comment;
- Final task force report to be released in January 2004. We intend to provide recommendations for public and private sector actions to address the problem of counterfeit drugs.

## II. Scope of Discussion

FDA is planning this public meeting in order to hear public comments on ways to combat counterfeit drugs. The objective of the meeting is for FDA to gather information to assist FDA's counterfeit drug task force in finalizing its report, which will include recommendations on steps that FDA, other government agencies, and the private sector can take to minimize the risks to the public from counterfeit drugs entering the supply chain. We anticipate that discussions at this meeting will include presentations from members of the public.

FDA plans to include with the task force interim report a series of questions specifically addressing the preliminary findings. The questions will be posted on FDA's Web site at [www.fda.gov](http://www.fda.gov). We request that presenters address these questions at the public meeting as well as the topics of interest listed in the following paragraphs. Specific topics of interest include, but are not limited to the following topics:

### *A. Technology*

1. What anti-counterfeit technologies currently are available for use as anti-counterfeit measures for pharmaceuticals (e.g., track/trace, authentication)?  
What are the costs associated with these technologies?
2. What is the current status of, and barriers to, adopting an industry standard for use of anti-counterfeiting technology?
3. What role should FDA play in facilitating the use of anti-counterfeit technologies and in the creation of an industry standard for use of anti-counterfeiting measures?

4. Should anti-counterfeiting measures be used for all drugs and biologics or just for drugs at high risk for counterfeiting? Is there a way to identify drugs at high risk for counterfeiting?

### *B. Regulatory and Legislative Issues*

1. In 2001, FDA submitted a report to Congress (<http://www.fda.gov/oc/pdma/report2001/default.htm>) on the status of the implementation and enforcement of the Prescription Drug Marketing Act (PDMA). As explained in this report, we raised concerns regarding implementation of the wholesale distribution provisions at 21 CFR 203.50, and these provisions have been stayed until April 2004. Have circumstances changed since the issuance of the report to Congress that could affect FDA's decision to continue the stay or implement these provisions?

2. How could PDMA be strengthened or augmented to reduce the risk of counterfeit drugs and biologicals from reaching consumers?

3. If PDMA were amended by Congress to require wholesale distributors to prepare and pass on a pedigree to all customers ("universal pedigree"), including to retail pharmacies, would the risk of distribution of counterfeit, expired, or otherwise unsuitable drugs to consumers be decreased?

4. How could state pharmacy practice acts be augmented or strengthened to minimize the introduction of counterfeit drugs into the drug distribution chain? Please give specific suggestions.

### *C. Public Education*

1. What are the information needs of consumers, trade groups, the media, state governments, manufacturers, wholesalers, pharmacists, and other health care professionals to help identify and report suspected counterfeit drugs?



2. What is the most effective and efficient way for FDA to notify the public and health professionals that a counterfeit product has been identified? What are the emergency messages that FDA should deliver to its various audiences when a report of a suspected counterfeit drug is received by the agency?

3. What types of communication tools are already in existence and/or should be developed to assist FDA in delivering its messages about counterfeiting?

4. How can FDA, other governmental agencies, and private stakeholders work together to create and disseminate education messages to various audiences (e. g. consumers, wholesalers, pharmacies) that are consistent while delivering the information that each stakeholder needs?

#### *D. Industry and Health Professional Issues*

1. What is the role of manufacturers, wholesalers, retailers, repackagers, and pharmacists in the following areas: (1) Identifying counterfeits, (2) preventing the introduction of counterfeits into the distribution chain, and (3) educating consumers. Should these stakeholders create in-house committees to develop and implement security and anti-counterfeit measures? Should stakeholders develop compliance programs?

2. Should a counterfeit drug alert network be developed? If so, should it be adapted from existing systems or should a new system be created? What would be the associated costs of adapting or creating a network?

We invite public comment on the overall FDA anti-counterfeit drug initiative, with a focus on the questions listed previously in this document.

### **III. Comments**

Interested persons may submit to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

Rockville, MD 20852, written or electronic comments by November 3, 2003.

Submit electronic comments to *<http://www.fda.gov/dockets/ecomments>*.

Groups should submit two copies. Individuals may submit one copy.

Comments are to be identified with the docket number found in brackets in the heading of this document. You should annotate and organize your comments to identify the specific questions to which they refer. To ensure timely handling, the outer envelope should be clearly marked with the docket number listed in the heading of this document along with the statement “Counterfeit Drug Meeting.” Comments to the docket can be reviewed in the Division of Dockets Management Monday through Friday between 9 a.m. and 4 p.m.

#### **IV. Transcripts**

You may request a copy of the transcript of the meeting in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 14 working days after the meeting at a cost of 10 cents per page or on compact disc at a cost of \$14.25 each. You can also examine the transcript Monday through Friday between 9 a.m. and 4 p.m. in the Division of Dockets Management.

**V. Electronic Access**

Persons with access to the Internet may obtain additional information on the public meeting at *<http://www.fda.gov/oc/initiatives/counterfeit/>*.

Dated: September 3, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**